

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 19/00		(11) International Publication Number: WO 95/27445
		(43) International Publication Date: 19 October 1995 (19.10.95)
<p>(21) International Application Number: PCT/IE95/00026</p> <p>(22) International Filing Date: 10 April 1995 (10.04.95)</p> <p>(30) Priority Data: S940328 8 April 1994 (08.04.94) IE</p> <p>(71) Applicant (for all designated States except US): BJORG CORPORATION [IE/IE]; 1 Stokes Place, St Stephen's Green, Dublin 12 (IE).</p> <p>(72) Inventor; and</p> <p>(75) Inventor/Applicant (for US only): LEAHY, Patrick [IE/IE]; 15 Derrynane, Glenart Avenue, Mount Merrion, Blackrock, County Dublin (IE).</p> <p>(74) Agent: CASEY, Lindsay, Joseph; F.R. Kelly & Co., 27 Clyde Road, Ballsbridge, Dublin 4 (IE).</p>		<p>(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, SK (Utility model), TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).</p> <p>Published With international search report.</p>
<p>(54) Title: APPARATUS FOR USE IN SURGERY</p> <p>(57) Abstract</p> <p>Apparatus (200) for use in surgery comprises a sleeve (202) having an entry opening (214) and an exit opening (205). The exit opening (205) has a first sealing means (211) for sealing the exit opening (205) around an incised wound of a patient. The entry opening (214) has a second sealing means (220) so as to enable a controlled environment within the sleeve (202) to be maintained when in use. In a preferred embodiment, the apparatus (200) comprises a second sleeve (232) having a first opening (238) and a second opening (234). The first sleeve (232) is locatable within the sleeve (202) with the second opening (234) being in communication with the entry opening (214). The first opening is locatable within the sleeve (202) being in a normally closed condition and capable of being in an open condition within the sleeve (202). A surgeon is capable of inserting a hand through the entry opening (214) (and simultaneously through the second opening (234)) into the second sleeve (232), through the first opening (238) and through the exit opening (205).</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mazernia
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

- 1 -

APPARATUS FOR USE IN SURGERY

The invention relates to an apparatus and method for use in surgery and in particular to an apparatus and method to be used in minimally invasive surgery in which surgery is carried out by making the smallest 5 incision possible in a patient's body generally referred to as laparoscopic surgery.

Abdominal surgery is generally carried out by making a relatively large incision allowing a surgeon 10 to enter the body cavity with both hands. Such surgery is traumatic for the patient and the healing process is lengthy. Some laparoscopic surgery such as hernia operations may be carried out by surgeons using minimally invasive techniques with trocar assemblies. 15 However, the techniques are generally complex and difficult and are not widely used.

According to the invention there is provided an apparatus for use in surgery comprising a sleeve having 20 an entry opening and an exit opening; a first sealing means for sealing the exit opening around an incised wound of a patient; a second sealing means for sealing the entry opening so as to enable a controlled environment within 25 the sleeve to be maintained in use.

In a particularly preferred embodiment of the invention the sleeve comprises a generally cylindrical device closed at one end thereof and the exit opening 30 is provided in a side wall of the sleeve adjacent to the closed end.

- 2 -

In one arrangement the exit sealing means comprises a flange around the exit for sealing against the body of a patient. Attached to the flange is a further sleeve with a ring member attached thereto which is insertable into an abdominal cavity. The ring member creates a seal to prevent escape of gas from the body cavity. Preferably the flange is provided with an adhesive for adhering to the body. Typically the flange is covered by a peel-off cover.

10

The entry sealing means may comprise a valve means through which a surgeon's arm may be inserted or through which a surgical instrument may be passed. Preferably the valve means is of a material which is sufficiently flexible to allow an arm to be passed therethrough and to seal against the arm when passed therethrough.

20
15

In one embodiment of the invention the entry sealing means comprises a first sealing element provided in the entry opening and a second sealing element provided on a surgical glove, the sealing elements inter-engaging to seal the sleeve of the glove on passing of the glove through the entry opening; the second flange providing a further sealing means.

The apparatus also provides a pressure differential means.

30

The invention will be more clearly understood from the following description thereof, given by way of example only with reference to the accompanying drawings in which:-

- 3 -

FIGURE 1 is a plan view of a first embodiment of an apparatus according to the invention;

5 FIGURE 2 is a cross-sectional view of the apparatus of Figure 1 of the drawings;

10 FIGURE 3 is a plan view of a second embodiment of an apparatus with an entry sealing means in position;

FIGURE 4 is a perspective view of the apparatus of Figure 3 in use;

15 FIGURE 5 is a perspective view of the entry sealing means of Figures 3 and 4 of the drawings in a first position of use;

20 FIGURE 6 is a side elevational view of the entry sealing means of Figure 5 of the drawings in an intermediate position of use;

25 FIGURE 7 is a perspective view of the sealing means of Figure 5 of the drawings in a second position of use;

FIGURE 8 is a perspective view of a third embodiment of an apparatus according to the invention;

30 FIGURE 9 is a side cross-sectional view of a fourth embodiment of an apparatus according to the invention;

35 FIGURE 10 is a perspective view of a fifth embodiment of an apparatus according to the invention in use;

- 4 -

FIGURE 11 is a plan view of the apparatus of
Figure 10 of the drawings;

5 FIGURE 12 is a cross-sectional view of the
apparatus of Figure 10 of the drawings shown in use;
and

10 FIGURE 13 is a cross-section view of the
apparatus of Figure 10 of the drawings shown in use.

15 Referring now to the drawings and in particular
to Figs. 1 and 2, there is shown an apparatus 1 which
comprises a sleeve 2 of flexible gas-impermeable
material. The sleeve 2 comprises a generally
cylindrical body closed at one end 3 thereof and open
at the other end 4. At the end 4 is defined an entry
opening 14 for enabling a surgeon's hand or surgical
instrument to be introduced into the sleeve 2. Near
the end 3 is provided an exit opening 5 having a
flexible flange 11 disposed coaxially relative thereto.
The flange 11 is in sealing engagement with the sleeve
2 the exposed face of the flange 11 having a suitable
adhesive material 10 thereon protected by a
peel-to-remove protective cover 12 thereon.

25 Referring now to Figures 3-7 of the drawings,
there is shown a second embodiment of an apparatus 100
according to the invention which is similar in
construction to the apparatus 1 except as follows.
30 Integral with end 4, there is provided an entry sealing
means 20. The sealing means 20 comprises a first
flange member 21 and a second flange member 22
interconnected by a flexible material which forms a
cuff 23.

- 5 -

Referring now to Figure 8 of the drawings, there is shown a third embodiment of an apparatus 50 according to the invention which is similar in construction to the apparatus 10 except as follows.

5 Integral with the end 4 is a first flange member 51. A surgeon's type glove or surgical glove 53 is provided having a second flange member 52 integral therewith in the region of the open end of the glove 53. Upon insertion of the glove 53 through the end 4, the 10 flanges 51, 52 are interengageable in a manner which will be described later in the specification.

Referring now to Figure 9 of the drawings, there is shown a fourth embodiment of an apparatus 60 according to the invention which is similar in construction to the apparatus 50 of Figure 8 of the drawings except as follows. A protector means 61 comprises an inner ring 63 and an outer ring 64 connected by a tube 62. The rings 63 and 64 are 20 integral with the tube 62 being located at respective ends thereof. Insertable into the exit opening 5 is the protector means 61.

The material of the tube 61 is the same type as 25 that of the rest of the sleeve 2.

Referring now to Figures 10-14 of the drawings, there is shown a fifth embodiment of an apparatus 200 according to the invention. The apparatus 200 30 comprises a sleeve 202. The sleeve 202 comprises a generally cylindrical body having a first end 203 thereof and a second end 204 thereof.

- 6 -

Near the end 203 is provided an exit opening 205 having a flange 211 disposed coaxially relative thereto. The flange 211 is in sealing engagement with the sleeve 202 the exposed face 213 of the flange 211 having a suitable adhesive material thereon protected by a peel-to-remove protective cover 212 thereon.

Within the sleeve 202, there is provided a second sleeve 232. The second sleeve also comprises a generally cylindrical body having a first end 233 and a second end 234.

The second sleeve 232 has sides or seams 236 and 237 which are in sealing engagement with the inner wall of the sleeve 202. In addition, the second end 204 of the sleeve 202 is in sealing engagement with the outer wall of the second sleeve 232 at a seam 241.

At the end 234 is defined an entry opening 214 for enabling a surgeon's hand 253 or surgical instrument to be introduced into the sleeve 232. Integral with the entry opening 234 is a flange element 220 which incorporates a cuff 221 similar to the cuff 20.

The first end 233 has an opening 238 which is of sufficient size to enable a hand to pass through. The opening 238 stops short of the location of the opening 214 and is preferably located approximately mid-way between the opening 214 and the opening 205.

Adjacent the opening 205 is provided an aperture 244 which is in communication with a tube 245. The tube 245 is disposed within the sleeve 202 and terminates in an opening 246 externally of the cuff 221. Through the side wall of the sleeve 202, a spur

- 7 -

tube 247 passes which is in communication with the tube 245.

The operation of the various embodiments will
5 now be described.

With reference to Figs. 1-7 of the drawings the device 1 or device 100 is used as follows.

10 An incision is first made in the abdomen 31 of a patient. The peritoneum is not cut. The wound is haemostatically secured. An incise drape is applied to the abdomen. An opening is made in the drape. The cover 12 is removed and the flange 11 adhesively bonded 15 to the drape around the incision so that the incision is in register with the opening 5. If a hand is now inserted through the opening 14, access to the incision in the abdomen 31 can now be achieved via the opening 5. The peritoneum is now cut and the interior of the 20 sleeve 2 is in communication with the interior of the abdomen 31. Because the wrist of the surgeon's hand effectively closes the opening 14, the gas in the abdomen will tend to inflate the interior of the sleeve 2 in the manner of a balloon and no gas can escape 25 through the opening 14. Thus, the abdomen 31 remains in an inflated condition thereby enabling appropriate surgery or investigative procedures to be carried out.

In order to enhance the sealing arrangement at 30 the opening 14 of the device 100, the cuff 23 is provided which, by its nature, tends to be more fully in interengagement with the wrist or arm of the surgeon's hand.

- 8 -

With particular reference to Figure 8 of the drawings, the device 50 may be used in a similar manner to the device 100. However, to even further enhance the sealing arrangement, and with particular reference to 5 Figure 8 of the drawings, the glove 53 together with the integral flange 52 is employed so that upon insertion of the surgeon's hand into the device 2, the flanges 51 and 51 are in sealing interengagement.

10 So as to further enhance the sealing arrangement at the site of the incision in the abdomen 3 and with particular reference to Fig. 9 of the drawings, following incision and before use of the device 60, the inner ring 63 is inserted into the wound, the outer ring 64 engages with the opening 5 inside the sleeve 2 with the flange 11 adhesively connected to the abdominal wall or drape as previously described. This 15 arrangement provides for an even more secure sealing arrangement.

20 With reference now to Figures 10-14 of the drawings, following the incision procedures referred to above, the flange 211 is offered and adhered to the abdomen 31 and the peritoneum is cut. Immediately the 25 sleeve 202 will inflate. However, because of the increase in pressure within the sleeve 202 and surrounding the second sleeve 232, the material of the second sleeve 232 at the opening 238 will be biased together so as to close the opening 238. Because the 30 end 244 of the tube 245 is in communication with the abdominal cavity, the spur 247 and the end 246 should be closed to prevent the escape of gases from the cavity.

Upon insertion of the surgeon's hand 300 through the cuff 221, the gas within the sleeve 202 remains in place until the hand 300 passes through the aperture 238 whereupon the gasses enter the second sleeve 232.

- 5 However, because the cuff 221 provides an effective seal around the surgeon's arm, gasses cannot escape any further and the abdominal cavity does not collapse. Access to the abdominal cavity via the opening 205 can now take place. Upon withdrawal of the surgeon's hand
10 through the aperture 238 and then through the opening 214, gasses will escape from the second sleeve 232 but as soon as there is the resulting fall in pressure in the second sleeve 202, the opening 238 will close and the pressure maintained within the abdominal cavity.
15 Essentially, therefore, the material of the second sleeve 232 at the opening 238 provides a third sealing means which together with the first sealing means define a substantially gas tight chamber or second sleeve 232 in communication with the opening 238.

20

- If desired, instruments may be inserted through the apparatus 200 in place of a hand 300 under the same operating conditions. If desired, carbon dioxide gas may be insufflated through the tube 245 and into the
25 abdominal cavity.

There are many advantages of the invention. Because a surgeon need only make a relatively small incision the trauma to the patient is minimised, there
30 is less risk of damage to the immune system and the healing time is short with a consequent decrease in the length of the hospital stay required. The techniques are considerably simpler than conventional laparoscopic surgical techniques and can be readily performed by a
35 surgeon with minimal additional training. A wide range

- 10 -

of operations can be performed using the apparatus of the invention. The surgeon is already trained to perform conventional surgery using his hand. The transition to assisted surgery is relatively easy.

5

It is anticipated that in some cases adhesive may be applied to a patient around the area of an incision to which a sealing ring of the sleeve is to be attached during preparations for an operation. Adhesive 10 may alternatively or additionally be applied to the ring to be attached around the area of an incision. Either or both layers of adhesive may be covered by a sterile wrapping material through which the incision may be made. Either or both layers of adhesive may be 15 provided with peel-off covers.

The inner flange with ring protects the wound and reduces gas release. It also enhances pneumoperitoneum.

20

It will further be appreciated that the sleeve may incorporate an air lock to facilitate changing of an instrument and/or debris such as cancer cells during an operation without breaking the sterilised 25 environment in the sleeve.

The inner walls of the sleeve or sleeves may incorporate a self-lubricating layer to reduce friction coefficient.

30

The sleeve (or sleeves) is designed to use both arms if the surgeon requires this.

- 11 -

CLAIMS:

1. An apparatus for use in surgery comprising a sleeve having an entry opening and an exit opening;
5 a first sealing means for sealing the exit opening around an incised wound of a patient;
a second sealing means for sealing the entry opening so as to enable a controlled environment within the sleeve to be maintained in use.
- 10 2. An apparatus as claimed in Claim 1 wherein the sleeve is of a flexible material.
- 15 3. An apparatus as claimed in Claim 1 or Claim 2 wherein the sleeve is of a gas-impermeable material to enable a controlled pressurised environment within the sleeve to be maintained.
- 20 4. An apparatus as claimed in any of Claims 1-3 wherein the first sealing means comprises a first flange member disposed coaxially relative thereto and having an exposed face for attachment around the wound.
- 25 5. An apparatus as claimed in Claim 4 wherein the first flange member is a flexible flange.
- 30 6. An apparatus as claimed in Claim 5 or Claim 6 wherein the exposed face has suitable adhesive material thereon for attachment of the first flange member around the wound.
7. An apparatus as claimed in Claim 6 wherein the adhesive material has a peel-to-remove protective cover thereon.

- 12 -

8. An apparatus as claimed in any of Claims 1-7 wherein the second sealing means comprises a second flange member and a third flange member.

5 9. An apparatus as claimed in Claim 8 wherein said second flange member and said third flange member are interconnected by a flexible material which forms a cuff.

10 10. An apparatus as claimed in claim 9 wherein the second flange member and the third flange member are rotatable relative to each other.

15 11. An apparatus as claimed in Claim 8 wherein the third flange member is integral with and secured around the opening of a surgical glove and wherein said second flange member and said third flange member are in sealing interengagement when the glove is located within the sleeve.

20 12. An apparatus as claimed in any of Claims 1-11 which further comprises a protector means insertable in the wound.

25 13. An apparatus as claimed in Claim 12 wherein said protector comprises a first ring and a second ring integral with, and interconnected by, a tube wherein, in use, the first ring is insertable into the wound, the second ring is locatable inside the sleeve so as to form a sealing arrangement between the body and the sleeve.

30 14. An apparatus as claimed in any of Claims 1-13 further comprising a second sleeve disposed within the

- 13 -

- sleeve, said second sleeve having a first opening and a second opening; the first opening being locatable inside the sleeve being in a normally closed condition and capable of being in an open condition inside the
5 sleeve; the second opening being in communication with the entry opening; the first opening providing a third sealing means which together with the first sealing means defines a substantially gas tight chamber in communication with the exit opening.
- 10 15. An apparatus as claimed in any of Claims 1-14 which further comprises a tube having a first end and a second end, the first end, in use, being in communication with the abdominal cavity of the patient;
15 the second end, in use, being in communication externally of the apparatus.
16. An apparatus as claimed in Claim 15 wherein the second end, in use, is connectable to a source of
20 carbon dioxide gas for introduction into the abdominal cavity and, consequently, the sleeve via the exit opening.
- 25 17. An apparatus as claimed in any of Claims 1-16 wherein the sleeve comprises a generally cylindrical device closed at one end thereof and the exit opening is provided in a side wall of the sleeve adjacent the closed end.

1/8

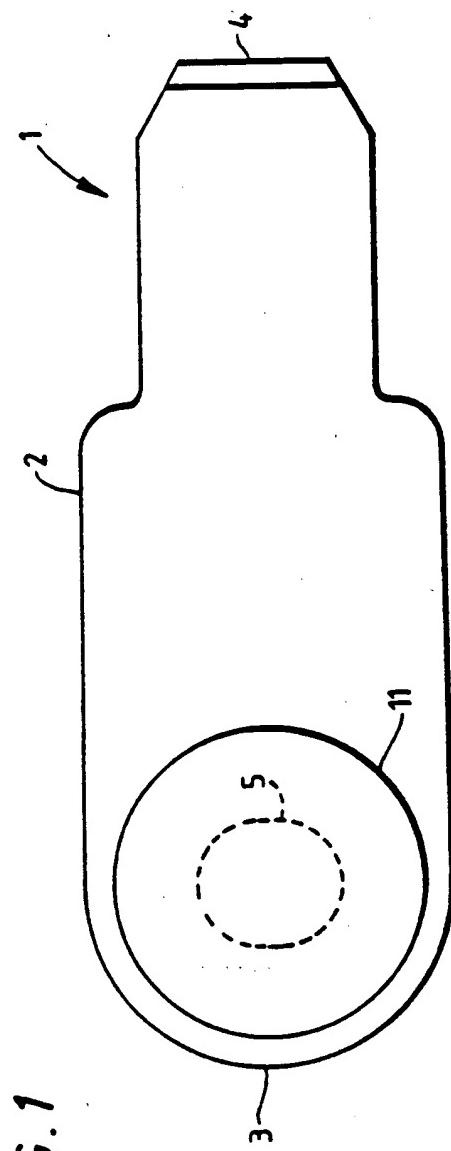


FIG. 1

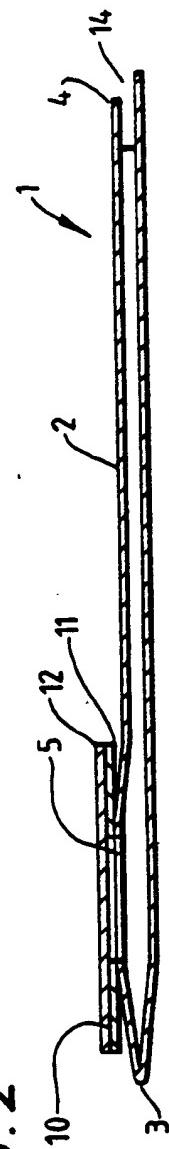
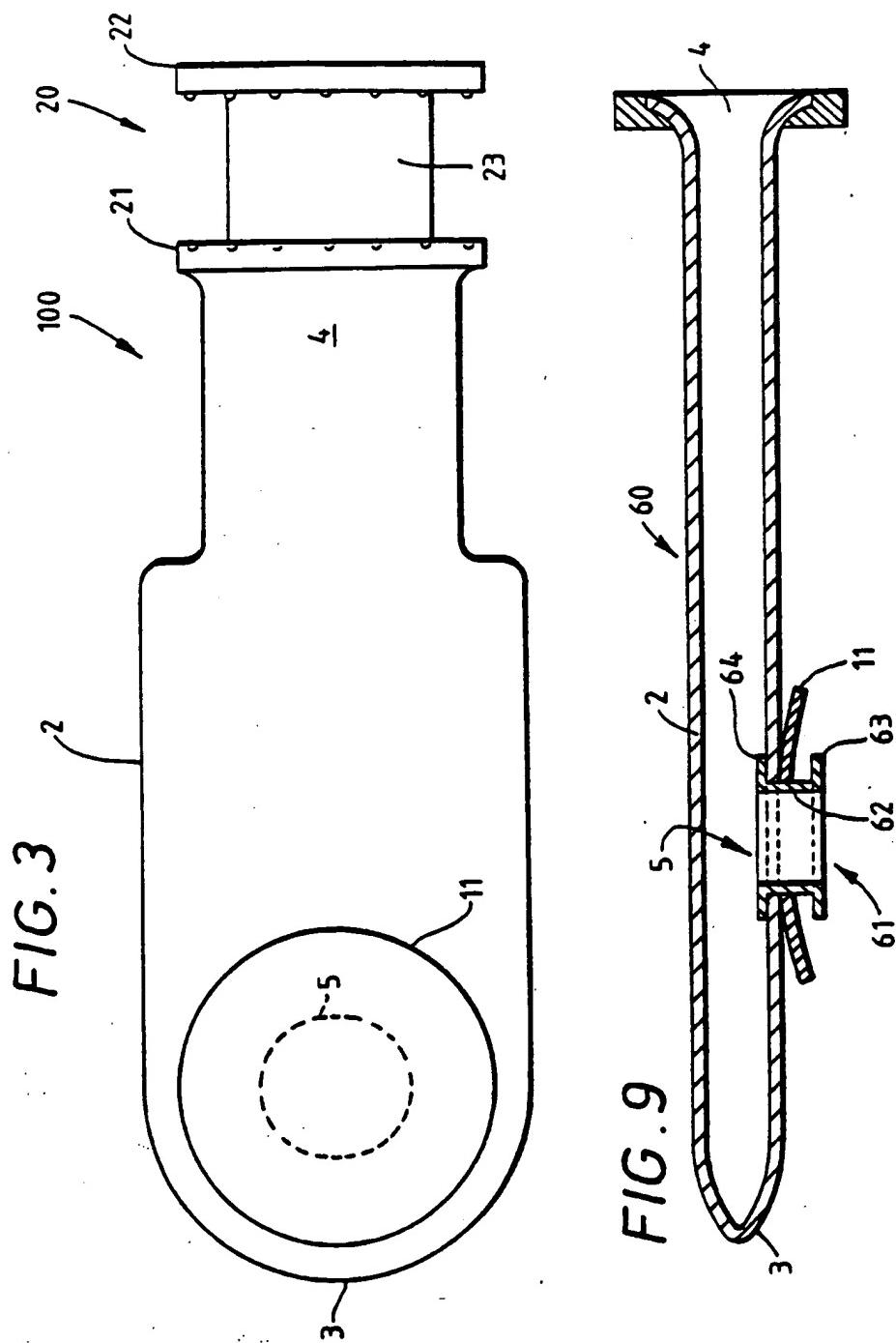


FIG. 2

SUBSTITUTE SHEET

2/8

**SUBSTITUTE SHEET**

3/8

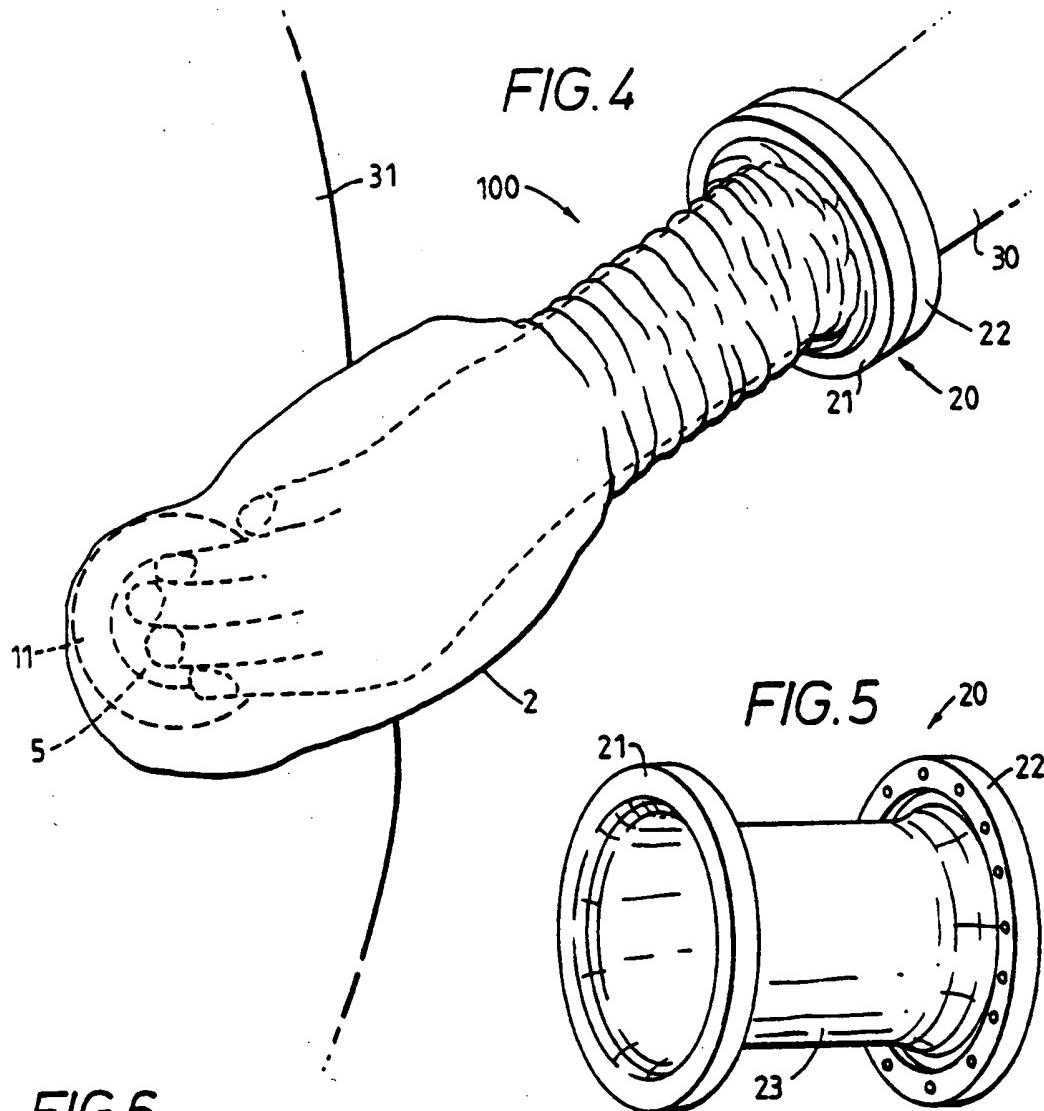
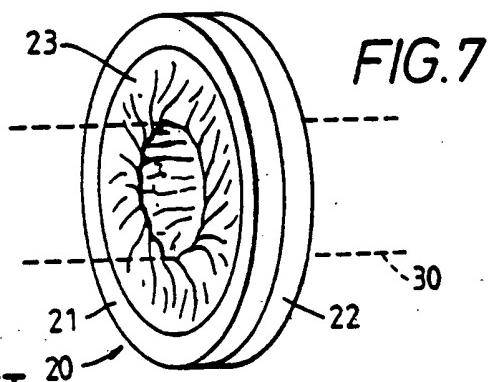
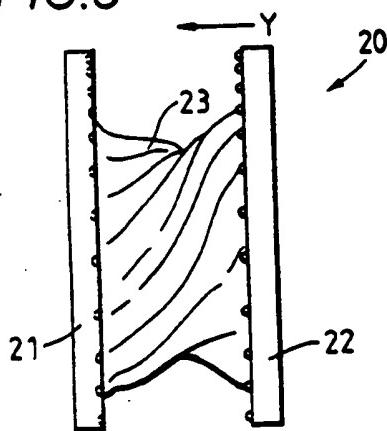
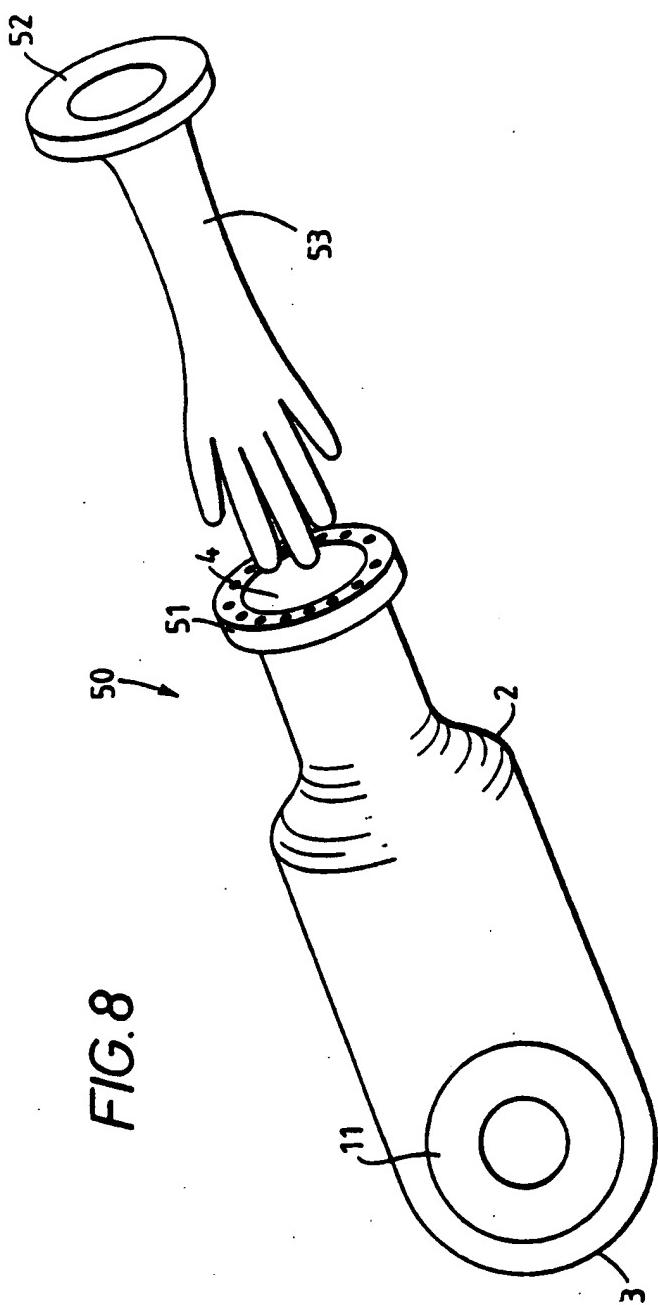


FIG. 6

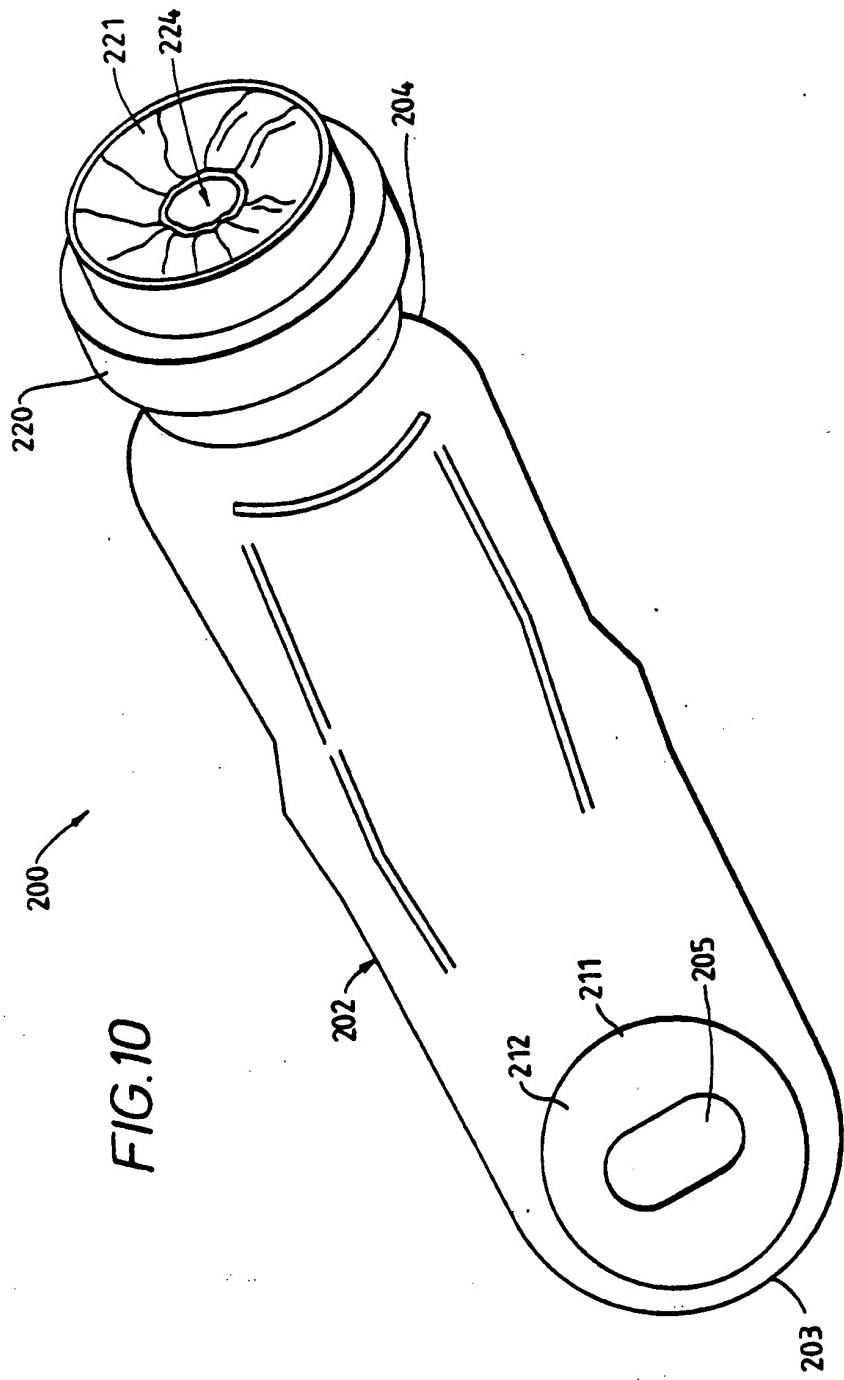


SUBSTITUTE SHEET

4/8

**SUBSTITUTE SHEET**

5/8

**SUBSTITUTE SHEET**

6/8

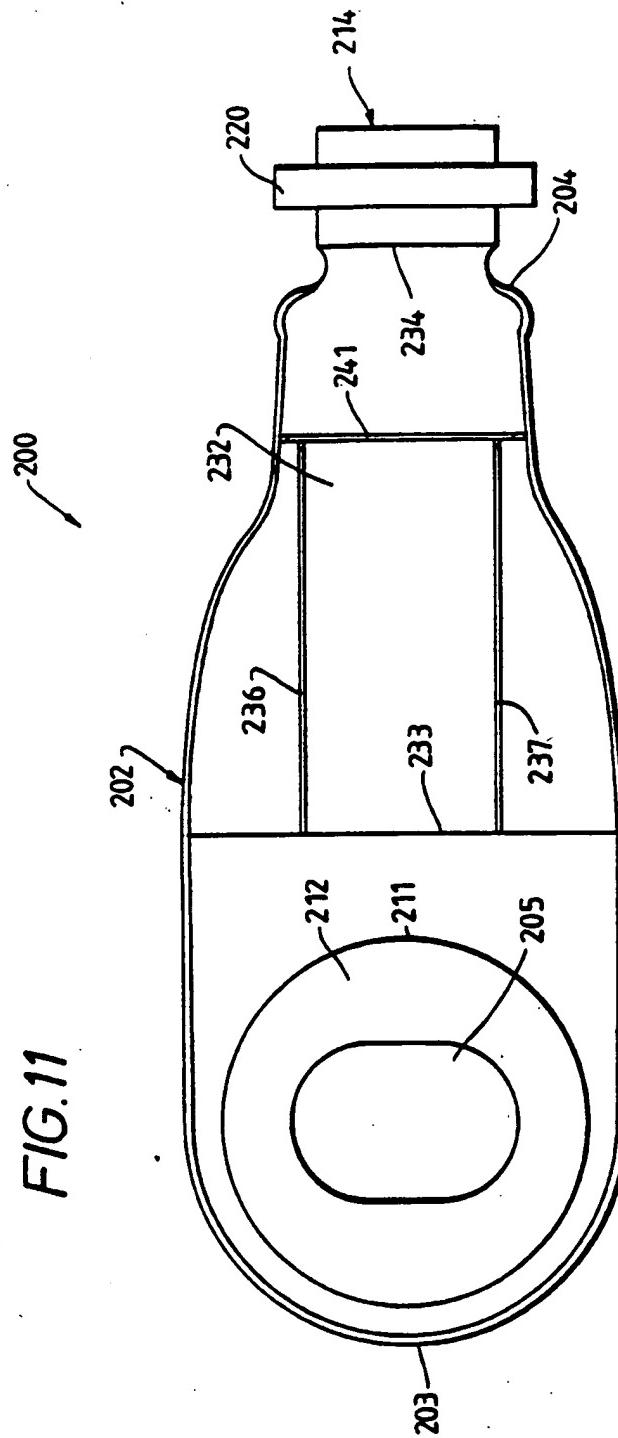
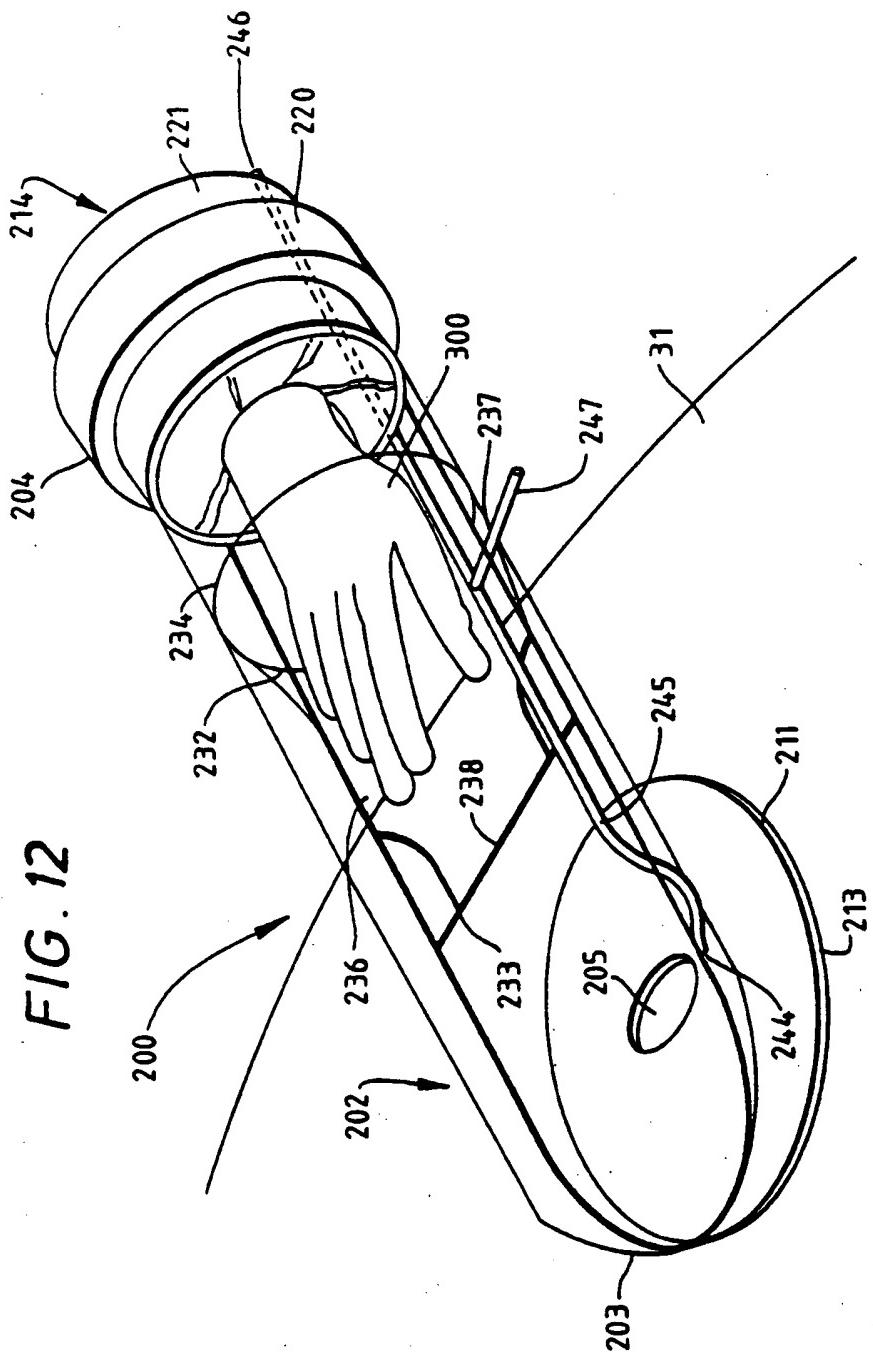


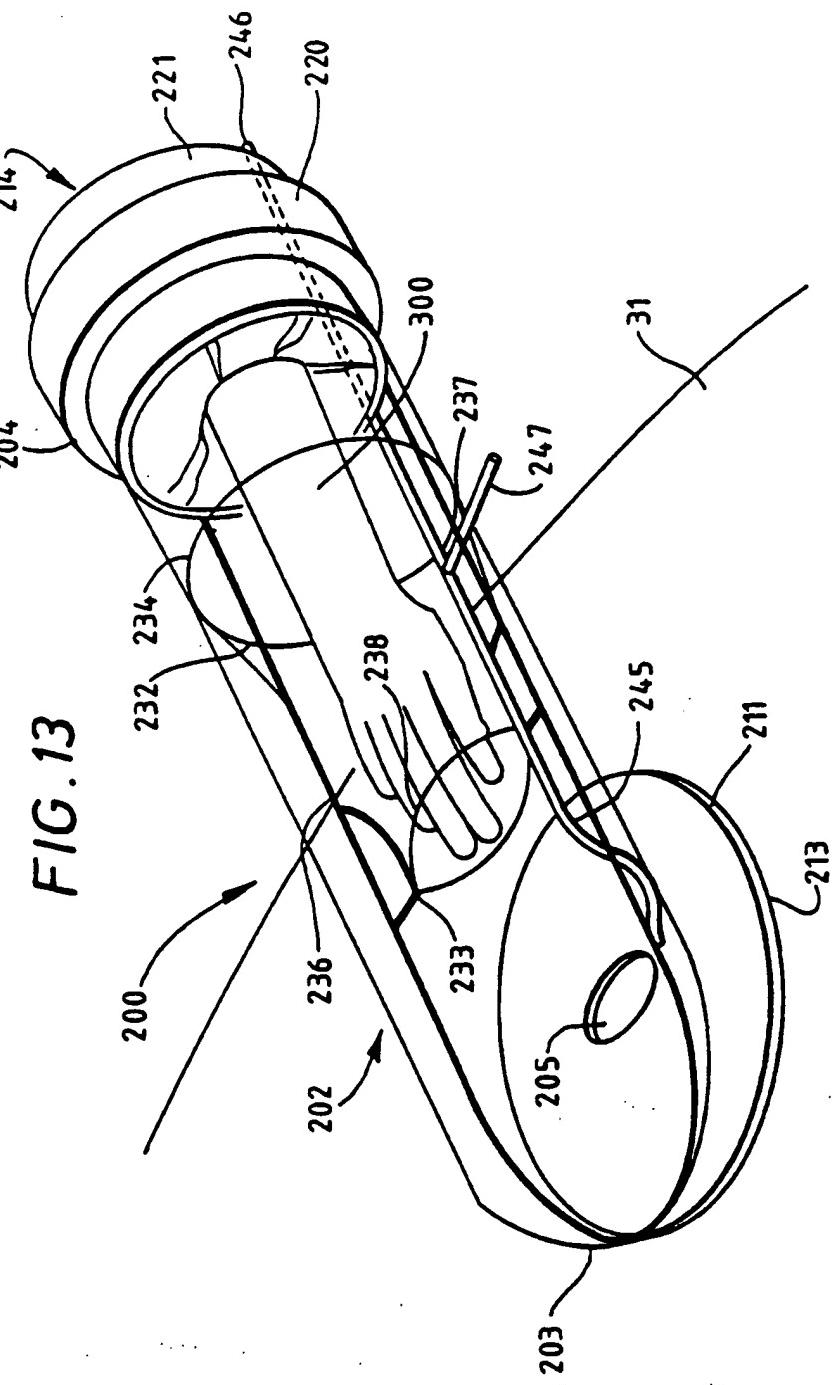
FIG. 11

SUBSTITUTE SHEET

7/8

**SUBSTITUTE SHEET**

8/8

**SUBSTITUTE SHEET**

INTERNATIONAL SEARCH REPORT

Internat'l Application No
PCT/IE 95/00026

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61B19/00
--

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
--

C. DOCUMENTS CONSIDERED TO BE RELEVANT
--

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO,A,95 07056 (ENCORET LTD.) 16 March 1995 see the whole document ---	1-17
X	WO,A,93 05740 (LITTLE RAPIDS CORP.) 1 April 1993 see page 6, line 3 - line 24; figures 1-3 ---	1,2,4-7
Y	US,A,2 695 608 (GIBBON) 30 November 1954 see column 2, line 27 - column 3, line 37; figures 1,2 ---	8-17
Y	GB,A,1 118 657 (IRWIN) 3 July 1968 see the whole document ---	8-17
X	WO,A,86 06272 (LONE STAR MEDICAL PRODUCTS) 6 November 1986 see page 8, line 9 - page 10, line 17; figures 1,2 ---	1-3
A	WO,A,86 06272 (LONE STAR MEDICAL PRODUCTS) 6 November 1986 see page 8, line 9 - page 10, line 17; figures 1,2 ---	1
		-/-

<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.
--

<input checked="" type="checkbox"/> Patent family members are listed in annex.
--

* Special categories of cited documents :

- 'A' document defining the general state of the art which is not considered to be of particular relevance
- 'E' earlier document but published on or after the international filing date
- 'L' document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- 'O' document referring to an oral disclosure, use, exhibition or other means
- 'P' document published prior to the international filing date but later than the priority date claimed

'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

'Z' document member of the same patent family

1

Date of the actual completion of the international search

Date of mailing of the international search report
--

18 July 1995

28.07.95

Name and mailing address of the ISA European Patent Office, P.O. Box 5818 Patentdienst 2 NL - 2280 HV Rijswijk Tel.: (+31-70) 340-2040, Fax: 31 651 epo nl, Fax: (+31-70) 340-3016
--

Authorized officer

Sánchez y Sánchez, J

INTERNATIONAL SEARCH REPORT

Internat'l Application No
PCT/IE 95/00026

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,4 998 538 (CHAROWSKY ET AL.) 12 March 1991 -----	
A	EP,A,0 142 262 (E.R. SQUIBB & SONS) 22 May 1985 -----	
A	US,A,2 835 253 (BORGESEN) 20 May 1958 -----	

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 95/00026

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9507056	16-03-95	AU-B-	7507494	27-03-95
WO-A-9305740	01-04-93	US-A- CA-A-	5299582 2119156	05-04-94 01-04-93
US-A-2695608	30-11-54	NONE		
GB-A-1118657		NONE		
WO-A-8606272	06-11-86	AT-T- DE-D- DE-T- EP-A- US-A-	106226 3689875 3689875 0224505 4950222	15-06-94 07-07-94 08-12-94 10-06-87 21-08-90
US-A-4998538	12-03-91	NONE		
EP-A-0142262	22-05-85	US-A- CA-A- DE-A- JP-C- JP-B- JP-A-	4553967 1262328 3470379 1803799 5010107 60100974	19-11-85 17-10-89 19-05-88 26-11-93 08-02-93 04-06-85
US-A-2835253	20-05-58	NONE		